U.S. Department of Justice
Civil Division, Federal Programs Branch

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Via ECF

Hon. Paul W. Grimm
U.S. District Court for the District of Maryland
6500 Cherrywood Lane, Suite 465A
Greenbelt, Maryland 20770

Re: *American Academy of Pediatrics v. FDA*, No. 8:18-cv-883-PWG

Dear Judge Grimm:

In accordance with the Court's letter order regarding the filing of motions (ECF No. 15), Defendants respectfully submit this letter describing their planned request for an indicative ruling on a Federal Rule of Civil Procedure 60(b) motion for a 120-day extension of the premarket application deadline imposed in the Court's remedy order (ECF No. 127) in light of the global outbreak of respiratory illness caused by a new coronavirus.

Under the Court's remedy order, the FDA must require that all premarket applications for new products be filed by May 12, 2020, and new products for which applications have been timely filed have a one-year period of enforcement discretion pending FDA review. ECF No. 127 at 12. The global coronavirus outbreak poses unforeseen challenges and has made the May 12 deadline a public health risk to those who cannot comply with the deadline through telework. As a result of the outbreak, many laboratories and contract research organizations, which perform required laboratory and clinical studies for manufacturers' premarket applications, have shut down or suspended in-person work indefinitely. 2d Mitchell Zeller Decl. ¶ 7. Coronavirus-related travel restrictions have hampered travel between offices and factories — in places like Italy, China, Honduras, the Dominican Republic, Nicaragua, and Mexico — to gather information for premarket applications. 2d Zeller Decl. ¶ 9. Factories in countries affected by the outbreak — like China, Honduras, and the Dominican Republic — have been unable to make timely deliveries of the tobacco products that manufacturers need for testing and premarket applications. 2d Zeller Decl. ¶ 9.

Moreover, as a result of the outbreak, some employees from the FDA's Center for Tobacco Products (CTP) have been deployed to work for the U.S. Public Health Service, including many within one of the divisions of CTP's Office of Science, which is responsible for reviewing premarket applications. 2d Zeller Decl. ¶ 13. Also, virtually the entire FDA staff responsible for reviewing premarket applications will be teleworking until further notice. 2d Zeller Decl. ¶ 13. While the FDA has taken steps to enable work to be performed remotely as much as possible, the agency anticipates that it will take additional time for a remote workforce to receive and process applications and conduct scientific review of those applications. 2d Zeller Decl. ¶ 13.

Defendants submit that these exceptional and unforeseen circumstances justify a 120-day extension of the premarket application deadline in the Court's remedy order under Federal Rule of Civil Procedure 60(b), which allows the Court to "relieve a party … from a final judgment [or]

order … for … any other reason that justifies relief."[1] Defendants therefore respectfully request that the Court issue an indicative ruling stating that if the Fourth Circuit were to remand the case, the Court would grant Defendants' Rule 60(b) motion and modify its remedy order to direct the FDA to require that, for new tobacco products on the market as of the August 8, 2016 effective date of the deeming rule ("New Products"), applications for marketing orders must be filed by September 9, 2020.[2] Defendants do not seek to modify any other deadlines in the Court's remedy order.[3]

Defendants seek this extension solely because of the coronavirus outbreak and would not do so but for these highly unusual circumstances. 2d Zeller Decl. ¶ 4. The FDA's current thinking about its enforcement priorities has not changed from the 2020 guidance (ECF No. 174-1), but the agency understands that the exceptional circumstances presented by the coronavirus outbreak warrant the extension. 2d Zeller Decl. ¶ 4.

Defendants consulted with Plaintiffs, who indicated that they do not intend to oppose the motion but wish to express their misgivings about the extension on the record and therefore request leave to file a response. *See* ECF No. 15 (stating that no response to a pre-motion letter should be filed without the Court's approval).

Defendants thank the Court for its attention to this matter.

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[1] Although this case is on appeal, Rule 62.1 allows the Court to issue an indicative ruling in these circumstances. *See* Fed. R. Civ. P. 62.1(a) ("If a timely motion is made for relief that the court lacks authority to grant because of an appeal that has been docketed and is pending, the court may … state … that it would grant the motion if the court of appeals remands for that purpose ….). If this Court states that it would grant the motion, the court of appeals may remand for further proceedings but would retain jurisdiction over the appeal. *See* Fed. R. App. P. 12.1(b).

[2] If Defendants' motion is granted, the FDA would intend to amend the 2020 guidance accordingly. 2d Zeller Decl. ¶ 15.

[3] Thus, under the Court's remedy order, new products for which applications are timely filed in accordance with this extended premarket application deadline would be subject to a one-year period of enforcement discretion while the FDA considers the application. ECF No. 127 at 12.

Respectfully submitted,

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